

Application No.: 09/843,638
Amendment Dated: July 8, 2004
Reply to Office Action of: May 19, 2004

In the Claims:

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with strikethrough (e.g. ~~deletion~~) and new text is identified in bold with underlining (e.g. new language).

Please amend claims 1, 13, 34, and 42 as follows:

1. (CURRENTLY AMENDED) An implantable therapy delivery system having an adjustable anchor, comprising:
an implantable therapy delivery device;
at least one therapy delivery element coupled to the implantable therapy delivery device;
an adjustable anchor coupleable to the therapy delivery element, the adjustable anchor being implantable and including,
a therapy grip element configured to be actuated to at least one of an open position or a closed position, the therapy grip element comprising a first portion and a second portion and having a length defined by the boundaries of a first and second opening, wherein in the open position the grip element comprises a discontinuous inner surface extending the length of the grip element and the first portion is separated from the second portion by a first distance, and wherein in the closed position the first portion is separated from the second portion by a second distance less than the first distance

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and the inner surface is configured to grippingly engage the

therapy delivery element,

at least two extension elements connected to the therapy grip element, the

extension element extending substantially perpendicular from the

therapy delivery element, and the extension elements being

configured to actuate the therapy grip element; and,

a tissue fixation element connected to the extension elements, the tissue

fixation element configured to be fixed to a tissue location from an

axial direction to the therapy delivery element.

2. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue.
3. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the two extension elements are actuated with a single pincer motion.
4. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the therapy delivery element is an electrical lead.
5. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the therapy delivery element is a catheter.
6. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the implantable therapy delivery device is a neurostimulator.
7. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the implantable therapy delivery device is a therapeutic substance delivery device.

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8. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the therapy delivery system performs the therapy of sacral nerve stimulation therapy.
9. (ORIGINAL) The implantable therapy delivery system as in claim 1 wherein the therapy delivery system performs the therapy of peripheral nerve stimulation therapy.
10. (PREVIOUSLY CANCELLED)
11. (PREVIOUSLY CANCELLED)
12. (PREVIOUSLY CANCELLED)
13. (CURRENTLY AMENDED) An adjustable anchor for a therapy delivery element, comprising:
 - a therapy grip element configured to be actuated to at least one of an open position or a closed position, the therapy grip element comprising a first portion and a second portion and having a length defined by the boundaries of a first and second opening, wherein in the open position the grip element comprises a discontinuous inner surface extending the length of the grip element and the first portion is separated from the second portion by a first distance, and wherein in the closed position the first portion is separated from the second portion by a second distance less than the first distance and the inner surface is configured to grippingly engage the therapy delivery element,
 - at least two extension elements connected to the therapy grip element, the extension element configured to extend substantially perpendicular from a

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therapy delivery element, and the extension elements being configured to

actuate the therapy grip element; and,

a tissue fixation element connected to the extension elements, the tissue fixation element configured to be fixed to a tissue location from an axial direction to the therapy delivery element.

14. (ORIGINAL) The implantable therapy delivery system as in claim 13 wherein the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue.
15. (ORIGINAL) The implantable therapy delivery system as in claim 13 wherein the two extension elements are actuated with a single pincer motion.
16. (ORIGINAL) The implantable therapy delivery system as in claim 13 wherein the therapy grip element has a substantially rigid grip surface.
17. (ORIGINAL) The implantable therapy delivery system as in claim 13 wherein the therapy grip element is configured in a normally closed position.
18. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element covers at least about 25 degrees of the therapy delivery element.
19. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element covers at least about 270 degrees of the therapy delivery element.
20. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element covers more than about 360 degrees of the therapy delivery element.

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21. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element has at least two friction pads that engage the therapy delivery element at substantially opposing angles.
22. (ORIGINAL) The implantable therapy delivery element as in claim 21 further comprising release tabs to unlock the therapy grip element before the therapy grip element is actuated from the a closed position to an open position.
23. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element further comprises a biasing element.
24. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy grip element has a grip stop surface that engages a complimentary extension stop surface to prevent the extension element from actuating the therapy grip element beyond a desired actuation limit.
25. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the extension element is positioned at less than about 180 degrees in relation to the therapy delivery element.
26. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the extension element is positioned at about 180 degrees in relation to the therapy delivery element.
27. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the tissue fixation element has a fixation configuration selected from the group consisting of a suture, a staple, and a screw.

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28. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the tissue fixation element is configured at a predetermined position in relation to the extension element.
29. (ORIGINAL) The implantable therapy delivery element as in claim 13 wherein the therapy delivery element has at least one anchor position reference.
30. (ORIGINAL) The implantable therapy delivery element as in claim 29 wherein the anchor position reference is selected from the group consisting of a visual reference, a tactile reference, an indentation, and a protrusion.
31. (PREVIOUSLY CANCELLED)
32. (PREVIOUSLY CANCELLED)
33. (PREVIOUSLY CANCELLED)
34. (CURRENTLY AMENDED) A method for anchoring a therapy delivery element, comprising:
- inserting a therapy delivery element having a length defined by the boundaries of a first and second opening into a human body;
- separating a first portion of a therapy grip element from a second portion of a therapy grip element to form a discontinuous inner surface extending the length of the therapy grip element by actuating two extension elements to open the therapy grip element;
- placing the therapy element within the inner surface of the therapy grip element;
- positioning the therapy grip element at a grip location on the therapy delivery element;

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closing the therapy grip element on the therapy delivery element by actuating the

two extension elements such that the inner surface of the grip element

grippably engages the therapy delivery element;

securing the therapy grip element on the therapy delivery element when the

therapy grip element is closed;

positioning a tissue fixation element at a tissue location;

fixing the tissue fixation element to tissue at the tissue location in an orientation

along the axial length of the therapy delivery element; and,

connecting the therapy delivery element to a therapy delivery device.

35. (PREVIOUSLY AMENDED) The method as in claim 34 further comprising sensing adjustable anchor location on the therapy delivery element while positioning the therapy grip element at the grip location on the therapy delivery element.
36. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue.
37. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the two extension elements are actuated with a single pincer motion.
38. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the therapy delivery device is a neurostimulator.
39. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the therapy delivery device is a therapeutic substance delivery device.

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40. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the therapy delivery element is a stimulation lead.
41. (PREVIOUSLY AMENDED) The method as in claim 34 wherein the therapy delivery element is a catheter.
42. (CURRENTLY AMENDED) A method for operating an adjustable anchoring for a therapy delivery element having a length defined by the boundaries of a first and second opening, comprising:
- separating a first portion of a therapy grip element from a second portion of a therapy grip element to form a discontinuous inner surface extending the length of the therapy grip element by actuating two extension elements to open the therapy grip element;
- placing the therapy element within the inner surface of the therapy grip element;
- positioning the therapy grip element at a grip location on the therapy delivery element;
- closing the therapy grip element on the therapy delivery element by actuating the two extension elements such that the inner surface of the grip element grippably engages the therapy delivery element;
- securing the therapy grip element on the therapy delivery element when the therapy grip element is closed;
- positioning a tissue fixation element at a tissue location; and,
- fixing the tissue fixation element to tissue at the tissue location in an orientation along the axial length of the therapy delivery element.

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43. (ORIGINAL) The method as in claim 42 further comprising sensing adjustable anchor location on the therapy delivery element while positioning the therapy grip element at the grip location on the therapy delivery element.
44. (ORIGINAL) The method as in claim 42 wherein the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue.
45. (ORIGINAL) The method as in claim 42 wherein the two extension elements are actuated with a single pincer motion.

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